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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ANDERSON, AMBER R				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/739,089

Applicant(s)

BALAS, CONSTANTINOS

Examiner

AMBER R. ANDERSON

Art Unit

3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/15/2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/02)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

1. The request for interference filed January 23, 2006 is acknowledged. However, examination of this application has not been completed as required by 37 CFR §41.102(a). Consideration of a potential interference is premature. See MPEP § 2303.
2. On November 23, 2005, the Office mailed a communication indicating that Claims 17-23 were in condition for allowance. However, a review of the application shows that the pending claims were actually Claims 17-22.
3. The November 23, 2005 Office action closed prosecution under *ex parte Quayle*. Applicant was required to file a response under 37 CFR § 41.202(a) regarding a potential interference with USP 6,902,935. Applicant's response, filed January 23, 2006, was non-responsive to that requirement. All of applicant's remarks in that communication were addressed to a potential interference with application 09/738,147, not to a potential interference with USP 6,902,935.

Continued Examination

4. In light of the problems noted above, and further in view of other problems not properly resolved over the entire period of prosecution, the previous indication of the allowability of the claims is withdrawn. Prosecution on the merits is reopened.
5. Claims 17-22 are pending. For purposes of this Office action, the claims submitted on February 12, 2003 are those which are currently considered to be pending and which have been examined for this Office action.

Interference

6. Applicant appears to have originally suggested an interference in a communication filed December 2, 2002. In a later communication (Feb 12, 2003), applicant stated Claims 17-22 corresponded to Claims 18, 19, 21, 27, 30 and 31 of US Pub 20020007122 (Kaufman et al.), which is application 09/738,147.
7. In the Quayle action, mailed November 23, 2005, applicant was instructed to comply with 37 CFR 41.202(a) regarding USP 6,902,935, which had issued less than five months earlier (June 7, 2005). Applicant's response did not address this requirement. Should currently pending Claims 17-22, in their present form, not claim substantially the same invention as has been granted in 6,902, 935, applicant may be barred under 35 USC 135 from introducing substantially the same invention now.

Priority

8. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:
- a. On December 15, 2000, applicant filed a specification containing a claim for priority "to U.S. provisional Application No. XXXXXX..."
 - b. Also on December 15, 2000, applicant filed a paper entitled, "Letter regarding rights of priority under 35 U.S.C. § 119(e)."

- c. In the Office action mailed January 6, 2003, an objection was made to applicant's claim of benefit to an unidentified U.S. provisional application pursuant to 35 USC 119(e).
 - d. In the January 6, 2003 communication, applicant was notified the declaration (oath) filed on August 30, 2001 was defective because it was incomplete. A new declaration was required.
 - e. On January 6, 2003, applicant was advised that a petition under 37 CFR §1.48 had not been filed to correct the inventorship in a provisional application. Therefore, applicant had not complied with 37 CFR § 1.78 or 1.48, and the "Letter" filed December 15, 2000 had not been accepted.
 - f. Applicant filed remarks (see page 8) on January 30, 2003, which included the statement, "...Applicant will take the appropriate steps to correct the deficiencies of the 'Related Applications' section of the specification and the Declaration, Petition and Power of Attorney as noted by the Examiner, prior to the issuance of this application."
9. Applicant has failed to take the appropriate steps, as previously required by the examiner. The objections to applicant's claim under 119(e) are being repeated, and applicant must take appropriate steps to correct these deficiencies in response to this Office action. Failure to do so will be treated as a deliberate omission, and practice under 37 CFR Sec 1.135(c) will not apply. The examiner "is without authority to postpone decision as to abandonment ... once an inadvertent omission is brought to the

attention of the applicant, the question of inadvertence no longer exists." (MPEP 714.03)

10. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119 (e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable

petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Foreign Priority

11. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Applicant filed an English translation of the Greek national application on June 13, 2003. On April 16, 2004, applicant filed a statement under 37 CFR 1.55(a)(4).

12. 37 CFR 1.55(a)(4)(ii) states "If an English language translation is required, it must be filed together with a statement that the translation of the certified copy is accurate." (Emphasis added.) As applicant filed a statement more than ten (10) months after the filing of the English translation, this filing does not comply with the rule requiring the translation "be filed together with a statement..." Therefore, applicant's statement under 1.55 (a)(4) is defective, and the foreign benefit claim has not been perfected.

13. As the examiner does not have the authority to waive a rule, applicant may wish to consider either filing a petition under 37 CFR 1.183 or refiling an English language translation accompanied by a statement the translation of the certified copy is accurate.

14. For purposes of this Office action, applicant's priority date remains December 15, 2000.

Priority showing under 37 CFR § 41.202(a)(4)

15. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e). Failure to provide a certified translation in compliance with § 41.154(b) may result in no benefit being accorded for the non-English application.

16. Again, the language from § 41.154(b) requires "a translation of the document into English and an affidavit attesting to the accuracy of the translation **must be filed with** the document." (Emphasis added.) Therefore, applicant's English translation has not been considered to be a form of evidence under § 41.154 because the translation was not accompanied with an affidavit attesting to its accuracy.

17. While applicant's submission under § 41.202 (a) (1-6), filed January 23, 2006 is considered to be non-responsive, as discussed above, it has been reviewed in regards to its priority showing under (a)(4). Applicant's showing is found on page 6 of that filing.

18. Applicant's priority showing is defective because

- The present application is not entitled to a priority date of March 28, 2000 until a proper certified translation in compliance with Sec 41.154(b) has been filed.

- The showing references an "Amendment and Response of January 3, 2003" but no such amendment is of record.
- Applicant's statement that an article "submitted by Applicant on November 25, 2002" does not appear to support a showing prior to March 28, **2000**.
- Applicant's statements regarding a business relationship are made without any accompanying statement, showing, or allegation that such events occurred prior to the earliest effective filing date of the other parties with which applicant has attempted to provoke an interference.

Other showings under 37 CFR 41.202(a)

19. While applicant's communication filed under § 41.202 was an improper response to the Office's requirement in the *ex parte Quayle* action, a brief review of the adequacy of applicant's showing is made here.

20. As noted in this action on the merits, Claims 17-22 are not considered to be patentable, so applicant has not identified a patentable count (41.202(a)(2)) and cannot identify a patentable claim from each party for each count ((a)(3)) because the applicant has relied on an application which does not contain patentable claims.

21. Applicant's showing under § 41.202(a)(3) found on pages 3-4 is insufficient. §41.203(a) states an interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa. Applicant states the term "applying" and "dispensing" "have the same ordinary meaning within the art." However, applicant fails to support this conclusion with any facts or other evidence.

22. Applicant's showing under (a)(3) for the second count is also deficient. On page 4, applicant states the proposed second count involves applicant's claim 20 and Kaufman's claim 27. The table on page 5 makes a comparison using Kaufman's Claim 27. However, the discussion on page 5 references Kaufman's claim 18 multiple times. It is also noted applicant had previously discussed Kaufman's claim 18 as corresponding to the first count previously.

23. Applicant's showing under 37 CFR § 41.202(a)(6) is deficient. From the record, it appears applicant wishes to be accorded a constructive reduction to practice date of March 28, 2000 (see discussion, p. 6), which corresponds to the filing date of the Greek Application No. 20000/00102. However the discussion on pp. 7-8 appears to only address support found in the current application, which has a filing date of December 15, 2000. Therefore, it is assumed applicant is only wishing to be accorded the benefit of December 15, 2000. This date is one year after the date of the application with which applicant is requesting a declaration of an interference.

24. Applicant is also advised that there appears to be no support in the Greek application for the tissue group to include "colorectal tissue." The only support for the general concept is found in the US application, page 18, line 2 where "colon" is mentioned. This may or may not be found to be equivalent to "colorectal tissue." Therefore, applicant's constructive reduction to practice date for Claim 22 is December 15, 2000.

25. Applicant is also advised that the Greek application, filed March 28, 2000, does not appear to contain the "Summary of the Invention" or the "Brief Description of the Drawings."

Inventorship issues

26. On November 10, 2009, applicant submitted a statement under 37 CFR 3.73(b) along with supporting documents. In those documents, "Dimitrios Pelecoudas" is listed as a party.

27. The Office's assignment records show an assignment was executed on August 14, 2002, with assignors being "Balas," Pelecoudas" and "The Foundation of Research and Technology Hellas." The papers submitted on November 10, 2009 are assumed to be the same as were filed with the Assignments Branch and are listed as recorded on November 10, 2009.

28. WIPO publication, WO 01/72214, published 4 October 2001, appears to list two inventors: Balas and Pelecoudas, and claims priority to Greek priority document 20000100102 (28 March 2000) and US application 09/739,089 (15 December 2000). The scope of the claims found in the international application appears to be of similar scope as the claims currently pending in this U.S. application.

29. Applicant filed at least two other U.S. applications: 10/240,367 and 12/368,647 which claim priority to the same Greek application (20000-100102), but which list joint inventorship as Balas and Pelecoudas.

30. Applicant is requested to clarify and confirm the inventorship of the claimed invention in this application in light of these differences in inventive entities and the assignment paperwork filed to that now listed in this U.S. application.

Evidence in the record

31. Applicant's attention is called to the guidance found in MPEP 716.01(c):

I. To be of probative value, any objective evidence should be supported by actual proof;

II. Attorney arguments cannot take the place of evidence and

III. Opinion evidence

32. Some of applicant's key allegations regarding the priority of invention are supported only by attorney remarks or arguments. See, for example, the following:

- 12/15/00 Letter regarding rights of priority
- 01/30/03 Amendment w/ remarks about inventorship dispute, applicant's business relationships, etc.
- 02/12/03 Amendment w/ remarks, pp. 5-6

33. Applicant's representative has made multiple conclusory statements unsupported by facts over this application's prosecution. Of particular note is the remark found on page 8, of the January 30, 2003 amendment stating "Applicant respectfully submits that Applicant is entitled to the December 15, 1999 priority date."

Filing under 37 CFR § 1.131

34. The declaration filed on December 2, 2002 under 37 CFR § 1.131 has been considered, but is ineffective to overcome the prior art references.

35. The 1.131 affidavit was filed in response to an action mailed August 23, 2002 containing rejections of Claims 1-16. All rejections were based upon the use of the reference USP 6,159,445 (Klaveness et al.) as either a 102 or 103 rejection. The examiner misstated on page 2 the grounds of rejection. Klaveness et al. was a reference under 35 USC 102(e), not 102(b), as was stated. It does not appear that applicant argued the Klaveness grounds of rejection in his response of December 2, 2002.

36. On December 2, 2002, applicant filed a declaration pursuant to 37 CFR § 1.131. It is not clear as to why applicant filed the 131 affidavit. It does not appear the examiner had made a rejection using any Kaufman publications (either 2002007122A1 or 20020127735A1). In the remarks accompanying the affidavit, applicant did not make any statement that the showing was being submitted to overcome the prior art reference, Klaveness et al.

37. On January 6, 2003, the examiner made a new grounds of rejection of Claims 1-5 as being anticipated under 102(e) using Kaufman et al. (Pub No. 2002/0127735). The examiner appears to have evaluated the affidavit relative to the Kaufman publications (see pp. 7-8).

38. In the final rejection mailed February 5, 2003, the examiner states why the applicant's declaration of December 2, 2002 filed under 37 CFR §1.131 was deficient. During the February 11, 2003 interview, the examiner requested applicant submit case law to support the legal conclusions regarding applicant's showing under 37 CFR §1.131.

39. The applicant filed an RCE and an amendment on February 12, 2003. However, it does not appear that applicant provided the examiner with the requested case law citations, as requested in the interview summary of February 11, 2003. Applicant's amendment cancelled Claims 1-16, and added Claims 17-22, which were copied from Kaufman et al. (20020007122A1, application # 09/738147).

40. Thereafter, the examiner does not appear to address the merits of the declaration filed on December 2, 2002. One possible reason the affidavit may have been no longer under consideration is that with applicant's statement that Claims 17-22 were copied from Kaufman, 09/738,147, the examiner may have determined that applicant could no longer use the affidavit under § 1.131 to establish prior invention. (See, 37 CFR 1.131(a)(1).) However, the record fails to show the examiner ever accepted the declaration under § 1.131 for its intended showing of prior invention to overcome a rejection under 35 USC 102 (a) or (e).

41. Applicant's declaration filed on December 2, 2002 is not acceptable for the reasons previously outlined in earlier Office communications. Also, the declaration was filed prior to Claims 17-22 being filed in the application and therefore, it cannot be relied upon to show prior invention for those claims. However, it does appear that the 1999 reference, which the declaration discusses, does disclose at least some of the claimed method for diagnosis found in Claims 17-22 now pending. Applicant's declaration filed under § 1.132 states this article was published in **December 1999**. Based upon applicant's own admission regarding the date of publication, this Balas et al. article may be used as prior art against applicant's current claims.

Filing under 37 CFR § 1.132

42. A declaration was filed on December 2, 2002 under 37 CFR § 1.132.
43. The prosecution history is similar to that as stated above for the treatment of the declaration under § 1.132. However, it does not appear the examiner ever made a rejection under 102(f) during the prosecution.
44. While applicant's declaration appears to address the matter of proper attribution related to the disclosure in a December 1999 publication, it is noted the current specification makes reference to a 1998 publication entitled, "In vivo assessment of acetic acid-cervical tissue interaction using quantitative imaging of back-scattered light: Its potential use for the in vivo cervical cancer detection grading and mapping" (see p. 5, lines 23-27). A review of the translation of applicant's Greek application appears to contain the same reference (page 6).
45. As both the U.S. application and the Greek application specify "the inventors" as "Balas, Dimoka, Orfanoudaki, and Koumantakis, applicant's December 2, 2002 declaration is not sufficient to establish inventorship relative to this 1998 publication.

Specification

46. The disclosure is objected to because of the following informalities: (note, these objections are in addition to the objection to the incomplete statement found on page 1 regarding the provisional application number).
- Page 1, line 27, "decease" should be —disease—
 - Page 2, line 29, "to" has been omitted after "difficult"
 - Page 3, line 12, should "Raman" be —Ramanajum--?

- Page 5, line 24, "koumandakis" should be capitalized
- Page 6, line 15, "are" (second occurrence) should be --do--
- Page 13, line 37, "figure" should be capitalized
- Page 14, "overimposed" would be better understood if changed to --superimposed--(lines 25, 26)
- Page 14, line 36, "bands" should be --band--
- Page 15, line 3, "it" is not a clear reference and line 5 "these" is not a clear pronoun
- Page 15, line 4, "caries" is misspelled
- Throughout the spec, "devises" should be changed to "devices" (e.g., page 15 and 18)
- Page 16, line 17, "consisted" should be changed to --consisting of--
- Page 16, line 24, "form" may be incorrect and should be --from--
- Page 16, line 31, "consisted" should be changed to --consisting--
- Starting with the last paragraph on page 16, the meaning of "adapted to" in this context is not understood. It may be a translational problem or should be otherwise explained.
- Page 17, line 9, "case" should be --cases--
- Page 17, line 17, "consisted" should be --consisting--
- Page 18, first paragraph, on line 4, the angle is described as "perpendicular" while on lines 5-6, an angle is described as being "a few degrees". Since 90

degrees is not the same as a "few degrees" applicant should review to see if something is omitted or misstated.

- Page 18, line 10, "are" should be deleted and "constituting" changed to – constitute--

Appropriate correction is required. In light of the numerous changes over the prosecution history and the possible changes to be made in response to this Office action, applicant is requested to provide a clean and marked up copy of a substitute specification incorporating all amendments to date.

Drawings

47. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the figures fail to show much of the detail described in the specification.

- Figure 1 is confusing or is missing details. On page 14, Figure 1 is described as having a curve ATC, but ATC is shown as part of "STI" and does not appear as expected on the plot of PV vs. T ("AT" is listed, but not "ATC").
- "NAT" appears on the plot of Figure 1, but not "NATC" as described on page 14. One possibility is that Figure 1 has reversed the NATC and NAT in that it makes some sense that NAT is that area of STI where no alteration took place, while NATC is the curve which should appear on the plot above.
- Figure 1 appears to encompass two figures, and therefore, the kinetics and parameters should be labeled as a separate figure from the top portion of the

view. Appropriate changes should also be made to the specification's brief description and detailed description.

- Figure 5's "II" and "IL" are so faint as to be confusing and illegible
- Figure 7 has lines which are too faint for reproduction (this also applies to other figures as well). Specifically, the return/reemitted line at the bottom is barely legible.

48. Applicant responded on January 30, 2003 to a drawing objection regarding the confusion over NAT and NATC. Applicant stated on page 6 that a substitute Figure 1 had been submitted, but no figure appears in the record showing that applicant filed a figure at that time.

49. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

50. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the automated triggering steps of Claims 17-19 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

51. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

52. Claims 17-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 17-20 of copending Application No. 10/978,101. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

53. Applicant has previously received a provisional double patenting rejection for claims in 10/346,338. Applicant must review all pending applications or patents to determine if any of the pending claims (currently Claims 17-22) read on any other claims in which this inventor is named. Applicant is to disclose these other patents or applications in the next response, and to identify those claims.

Claim Rejections - 35 USC § 112, 1st Paragraph

54. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Critical Features not Claimed (MPEP 2164.08(c))

55. Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Appropriate means for ensuring the stability of the relative position between the tissue surface and image capturing module during the snapshot imaging procedure has been described as critical or essential to the practice of the invention, but because these limitations are not included in the claim(s) they are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See specification, p. 6, line 19, for example, where applicant makes various statements regarding criticality: "This is very important..." and p. 17, line 6. To further support this criticality, the Greek application's English translation states this to be "A **serious** problem..."

56. Claims 20-22 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Regarding the clinical implementation of the diagnostic method, "an important issue" "is the synchronization of the application of the contrast enhancing agent with the initialization of the snapshot imaging procedure." See specification, page 17, line 29. Therefore, the disclosure stated that during the snapshot procedure, dispensing the contrast enhancing agent in synchronization with imaging was critical. This language is construed as describing limitations that are critical or essential to the practice of the invention, but which have not been claimed.

57. Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. It appears that on pages 15-16 and on page 18 (lines 21-25) that applicant is stating that the processing must include a critical method step of linearly polarizing the light so as to overcome the problems associated with surface reflections negatively impacting the captured image. The claims do not include such steps.

New Matter

58. Claims 17-19, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

59. Applicant does not appear to have disclosed an explicit step of "providing an automated triggering signal" (Claims 17-19) or of having a measuring step which "is performed at predetermined times relative to said dispensing step" (Claim 21).

60. Regarding the language of Claim 17, the original disclosure does not explicitly disclose the step of 1) automated generation of a triggering signal and 2) the triggering signal initiates a measurement periods relative to the step of applying an agent on the tissue. The claim language is much more specific than what was originally disclosed.

61. Regarding the language of Claim 21, the measuring step is claimed for the embodiment involving the capturing of sequential images (Claim 20). Claim 20 states a measuring step involves measuring the evolution of the optical signal over time after the

images have been spatially correlated. According to Claim 21, that measuring step is performed at predetermined times relative to dispensing the agent on tissue. The original disclosure fails to support the concept that the measuring step can occur at predetermined times relative to the dispensing step. The specification appears to support the concept that there is synchronization between the application of the agent to the tissue and the taking of the snapshots (see, for example, page 17, lines 29-37), but that is different from what Claim 21 is claiming.

62. Applicant's statements filed on January 23, 2006 to comply with 37 CFR § 41.202(a)(5) are noted, but these statements are insufficient to establish support for these particular limitations. It is also noted that the record includes an interview summary for an interview held on 11 February 2003 in which applicant's representative was first advised that newly proposed Claim 17 included a step of "providing an automated triggering signal..." that raised new issues.

63. While not a rejection, applicant is advised that Claim 22 appears to lack support in the Greek application for the use of the method for colorectal tissue.

Claim Rejections - 35 USC § 112, 2nd Paragraph

64. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

65. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the measuring step of Claim 21 occurs during the process of Claim 20. It appears that the order of steps in Claim 20

is essential, and cannot be reordered or else the process would not function. So, the plurality of images must be snapped, those images must be aligned (calibrated) and then measurements made of the changes in the optical signal over the time period the images were captured. So, it is unclear how the measuring step can be performed at predetermined times relative to the dispensing step when measurements cannot be performed until images are taken and images calibrated.

Claim Rejections - 35 USC § 102

66. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

67. For purposes of these rejections, applicant's constructive reduction to practice date has been determined to be **December 15, 2000** except for those claim limitations discussed above for Claims 17-19 and 21, which are considered to be new matter.

68. Claims 20-22 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Balas et al. publication in Journal of Photochemistry dated December 1999 (see

applicant's admissions in declarations filed under § 1.131 and 1.132 on December 2, 2002. It is noted applicant submitted the article to the publisher on 14 September 1999, but the exact publication date is unknown other than it was sometime in December 1999. Therefore, if it occurred prior to December 15, 1999, the reference may serve as a bar under 102(b).

69. Claims 20-22 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. Balas et al. publication in Journal of Photochemistry dated December 1999. As applicant's U.S. filing date is considered to be December 15, 2000, the article discloses events which occurred in public at least before September 1999 (the article's submission date), which is more than one year prior to the U.S. filing date. The method described in the article is not considered to be experimental in light of the statements found in section 4 that "the method described here is capable of..." and the fact that the "further research" addresses matters not part of the claimed invention.

70. An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows: the time periods during which the two groups of patients were examined using the inventive method of analysis described in the 1999 Balas et al. document should be provided in response to this Office communication.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

71. Claims 17-22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kaufman et al. 2002/0007122. As discussed previously, applicant's declaration under 37 CFR § 1.131 is not accepted for its purported showing. Also, applicant's claim for priority to the Greek application has not yet been properly perfected (but this step would still not remove this grounds of rejection).

72. Claims 17-19 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Applicant's U.S. application and the prior Greek application (dated March 28, 2000) do not show possession of a method of providing an automated triggering signal relative to an applying step. This limitation was copied from the disclosure of Kaufman et al. and therefore, it does not appear applicant invented the currently claimed subject matter of Claims 17-19.

73. Claim 21 is rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Applicant's U.S. application and the prior Greek application (dated March 28, 2000) do not show possession of a method of providing a measuring step at predetermined times relative to the dispensing step.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER R. ANDERSON whose telephone number is (571) 270-5281. The examiner can normally be reached on Mon-Thur, 8am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Welch can be reached on (571) 272-4996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AMBER R ANDERSON/
Examiner, Art Unit 3765

September 15, 2010

/GARY L. WELCH/
Supervisory Patent Examiner, Art Unit 3765